IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

KOWA COMPANY, LTD., KOWA PHARMACEUTICALS AMERICA, INC. and NISSAN CHEMICAL INDUSTRIES, LTD.,	)	Civil Action No. _____
Plaintiffs,	)	
v.	)	
ORIENT PHARMA CO., LTD.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs, Kowa Company, Ltd. ("KCL"), Kowa Pharmaceuticals America, Inc. ("KPA")(collectively, "Kowa"), and Nissan Chemical Industries, Ltd. ("NCI") by their undersigned counsel, for their Complaint against defendant Orient Pharma Co., Ltd. ("Orient"), allege as follows:

Jurisdiction and Venue

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code and arising under 35 U.S.C. §§ 271(e)(2), 271(b), 271(c), and 281-283. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391 (c)(3) and 1400(b). Personal jurisdiction over the defendant in Chicago and this district is proper based on defendant's designation of an agent for service of process in this jurisdiction, 735 ILCS 5/2-209, and/or Fed. R. Civ. P. 4(k)(2).

Parties

2. KCL is a Japanese corporation having its corporate headquarters and principal place of business in Aichi, Japan. KPA is a wholly owned U.S. subsidiary of KCL. KPA has its

corporate headquarters and principal place of business in Montgomery, Alabama and is organized under the laws of Delaware.

3. NCI is a Japanese corporation having its corporate headquarters and principal place of business in Tokyo, Japan.

4. KCL and NCI are engaged in the business of research, developing, manufacturing, and marketing of a broad spectrum of innovative pharmaceutical products, including Livalo®.

5. Upon information and belief, Orient is a corporation organized and existing under the laws of Taiwan having a place of business in Taipei, Taiwan. Upon information and belief, Orient filed Abbreviated New Drug Application ("ANDA") No. 20-5932.

6. Upon information and belief, Orient intends to transact business in the Northern District of Illinois, at least by making and shipping into this Judicial District, or by using, offering to sell or selling or by causing others to use, offer to sell or sell, pharmaceutical products into this Judicial District.

7. Upon information and belief, Orient will derive substantial revenue from interstate and/or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of Illinois and the Northern District of Illinois. Orient has also designated "an agent authorized to accept service of process" pursuant to 21 C.F.R. § 314.95(c)(7) in Chicago, Illinois. By filing its ANDA, Orient has committed, and unless enjoined, will continue to commit a tortious act without the state of Illinois, that Orient expects or should reasonably expect to have consequences in the State of Illinois including in this Judicial District.

The New Drug Application

8. KPA sells drug products containing pitavastatin calcium (the "pitavastatin drug product") under the trade name Livalo® in the United States pursuant to the United States Food and Drug Administration's approval of a New Drug Application ("NDA") held by KCL (NDA No. 22-363).

9. Livalo® is approved for use as an adjunctive therapy to diet to reduce elevated total cholesterol, low-density lipoprotein cholesterol, apolipoprotein B, triglycerides, and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia.

10. The approval letter for Livalo®, with approved labeling, was issued by the FDA on August 3, 2009.

11. Certain amendments to the approved labeling for Livalo® have subsequently been approved.

The Patents in Suit

12. United States Patent No. 5,856,336 ("the '336 patent"), entitled "Quinoline Type Mevalonolactones," a true and correct copy of which is appended hereto as **Exhibit A**, was duly issued on January 5, 1999 to inventors Yoshihiro Fujikawa, Mikio Suzuki, Hiroshi Iwasaki, Mitsuaki Sakashita, and Masaki Kitahara, and assigned to plaintiff NCI. The '336 patent claims, *inter alia*, the pitavastatin drug product, and a method for reducing hyperlipidemia, hyperlipoproteinemia or atherosclerosis, which comprises administering an effective amount of the pitavastatin drug product.

13. Plaintiff NCI has been and still is the owner through assignment of the '336 patent, which expires on December 25, 2020 pursuant to a patent-term extension. KCL is NCI's licensee for the '336 patent and KPA holds a license from KCL for the '336 patent.

14. United States Patent No. 6,465,477 ("the '477 patent"), entitled "Stable Pharmaceutical Composition," a true and correct copy of which is appended hereto as **Exhibit B**, was duly issued on October 15, 2002 to inventors Toyojiro Muramatsu, Katsumi Mashita, Yasuo Shinoda, Hironori Sassa, Hiroyuki Kawashima, Yoshio Tanizawa, and Hideatsu Takeuchi, and jointly assigned to plaintiffs KCL and NCI. The '477 patent claims, *inter alia*, pharmaceutical compositions containing pitavastatin salts.

15. Plaintiffs KCL and NCI have been and still are the owners through assignment of the '477 patent, which expires on December 20, 2016. KPA holds a license from KCL for the '477 patent.

16. United States Patent No. 8,557,993 ("the '993 patent"), entitled "Crystalline Forms of Pitavastatin Calcium," a true and correct copy of which is appended hereto as **Exhibit C**, was duly issued on October 15, 2013 to inventors Paul Adriaan Van Der Schaaf, Fritz Blatter, Martin Szelagiewicz, and Kai-Uwe Schoening, and ultimately was assigned to plaintiff NCI. The '993 patent claims, *inter alia*, crystalline polymorphs or the amorphous form of pitavastatin or processes for preparing the same.

17. Plaintiff NCI has been and still is the owner through assignment of the '993 patent, which expires on February 2, 2024. KCL is NCI's licensee for the '993 patent and KPA holds a license from KCL for the '993 patent.

18. In accordance with its license, KPA sells the pitavastatin drug product under the trade name Livalo® in the United States. Sales of Livalo® are made pursuant to approval by the FDA of NDA No. 22-363.

19. Plaintiff KCL manufactures the Livalo® drug products as sold by KPA.

20. Plaintiffs Kowa and NCI will be substantially and irreparably harmed by infringement of any of the '336, '477, or '993 patents (the "Livalo® patents"). There is no adequate remedy at law.

COUNT I

INFRINGEMENT OF THE '336 PATENT UNDER 35 U.S.C. § 271(e)(2)(A)

21. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

22. Upon information and belief, defendant Orient filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j) (ANDA No. 20-5932) seeking approval to market 1 mg, 2 mg, and 4 mg tablets comprising pitavastatin calcium.

23. By this ANDA filing, Orient has indicated that it intends to engage, and that there is substantial likelihood that it will engage, in the commercial manufacture, importation, use, offer for sale, and/or sale, or inducement thereof, of Plaintiffs' patented pitavastatin drug product immediately or imminently upon receiving FDA approval to do so. Also by its ANDA filing, Orient has indicated that its drug product is bioequivalent to Plaintiffs' pitavastatin drug product.

24. By its ANDA filing, Orient seeks to obtain approval to commercially manufacture, use, import, offer for sale, and/or sell, alleged generic equivalents of Plaintiffs' Livalo® pitavastatin drug product prior to the expiration date of the '336 patent.

25. By a letter dated March 20, 2014 (the "Notice Letter"), Orient informed Kowa and NCI that Orient had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I). On or about March 21, 2014, KPA received the Notice Letter. On or about March 24, 2014, KCL and NCI received the Notice Letter.

26. The Notice Letter, purporting to be Orient's Notification Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), asserts that in Orient's opinion, the '336 patent purportedly is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale or importation of the drug products described in Orient's ANDA."

27. Orient's filing of ANDA No. 20-5932 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer for sale and/or sale, or inducement thereof, of its proposed pitavastatin drug product before the expiration of the '336 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

28. Orient's manufacture, use, importation, offer for sale, and/or sale, or inducement thereof, of its proposed pitavastatin drug product will directly infringe or induce infringement of at least one claim of the '336 patent under 35 U.S.C. § 271(e)(2)(A).

29. Upon information and belief, Orient's proposed label for its pitavastatin drug product will include the treatment of at least one of hyperlipidemia, hyperlipoproteinemia, and atherosclerosis.

30. Unless Orient is enjoined from infringing and inducing the infringement of the '336 patent, Plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II

INFRINGEMENT OF THE METHOD CLAIM OF THE '336 PATENT UNDER 35 U.S.C. § 271(b)

31. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

32. Upon information and belief, approval of ANDA 20-5932 is substantially likely to result in the commercial manufacture, use, importation, offer for sale, and/or sale, or inducement

thereof, of a pitavastatin drug product which is marketed and sold for use in a method claimed in one or more claims of the '336 patent, immediately or imminently upon approval of the ANDA, and prior to the expiration of the '336 patent.

33. Upon information and belief, Orient's proposed label for its pitavastatin drug product will include the treatment of at least one of hyperlipidemia, hyperlipoproteinemia or atherosclerosis.

34. Upon information and belief, Orient is aware or reasonably should be aware, of the widespread use of pitavastatin as an adjunctive therapy to diet to reduce elevated total cholesterol, low-density lipoprotein cholesterol, apolipoprotein B, triglycerides, and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia. The beneficial effects of pitavastatin as an adjunctive therapy to diet to reduce elevated total cholesterol, low-density lipoprotein cholesterol, apolipoprotein B, triglycerides, and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia would be readily apparent to customers of Orient (*e.g.*, including, without limitation, physicians, pharmacists, pharmacy benefits management companies, health care providers who establish drug formularies for their insurers and/or patients). Orient will be marketing its pitavastatin drug product with specific intent to actively induce, aid and abet infringement of the '336 patent. Orient knows or reasonably should know that its proposed conduct will induce infringement of the '336 patent.

35. Unless Orient is enjoined from infringing and inducing the infringement of the '336 patent, Plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III

INFRINGEMENT OF THE METHOD CLAIM OF THE '336 PATENT UNDER 35 U.S.C. § 271(c)

36. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

37. Upon information and belief, Orient's proposed pitavastatin drug product comprises pitavastatin calcium as referenced in the claims of the '336 patent.

38. Upon information and belief, Orient's proposed pitavastatin drug product will be especially made for use in a manner that is an infringement of the '336 patent.

39. Upon information and belief, Orient knows that Orient's proposed pitavastatin drug product will be especially made for use in a manner that is an infringement of the '336 patent.

40. Upon information and belief, sale of Orient's proposed pitavastatin drug product will result in direct infringement of the '336 patent.

41. Upon information and belief, Orient's proposed pitavastatin drug product is not a staple article or commodity of commerce which is suitable for a substantial noninfringing use.

42. Upon information and belief, Orient knows that Orient's proposed pitavastatin drug product is not a staple article or commodity of commerce which is suitable for substantial noninfringing use.

43. Upon information and belief, approval of ANDA 20-5932 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale (or the inducement thereof or contribution thereto) of a drug product which is especially made, adapted, marketed, sold, and approved exclusively for use in a method claimed in the '336 patent, immediately or imminently upon approval of the ANDA.

44. Plaintiffs will be substantially and irreparably harmed if defendant is not enjoined from contributing to the infringement of the '336 patent. Plaintiffs have no adequate remedy at law.

COUNT IV

INFRINGEMENT OF THE '477 PATENT UNDER 35 U.S.C. § 271(e)(2)(A)

45. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

46. Orient's Notice Letter, purporting to be Orient's Notice of Certification under 21 U.S.C.§ 355(j)(2)(B)(ii), indicates that Orient intends to manufacture, use, sell, or offer for sale, its proposed pitavastatin drug product prior to the expiration of the '477 patent.

47. The Notice Letter asserts that in Orient's opinion, the '477 patent purportedly is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale or importation of the drug products described in Orient's ANDA."

48. Orient's filing of ANDA No. 20-5932 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer for sale and/or sale, or the inducement thereof, of its proposed pitavastatin drug product before the expiration of the '477 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

49. Orient's manufacture, use, importation, offer for sale, sale, and/or importation of its proposed pitavastatin drug product will directly infringe or induce infringement of at least one claim of the '477 patent under 35 U.S.C. § 271(e)(2)(A).

50. Unless Orient is enjoined from infringing the '477 patent, Plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT V

INFRINGEMENT OF THE '993 PATENT UNDER 35 U.S.C. § 271(e)(2)(A)

51. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

52. Orient's Notice Letter, purporting to be Orient's Notice of Certification under 21 U.S.C.§ 355(j)(2)(B)(ii), indicates that Orient intends to manufacture, use, sell, or offer for sale, its proposed pitavastatin drug product prior to the expiration of the '993 patent.

53. The Notice Letter asserts that in Orient's opinion, the '993 patent purportedly is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale or importation of the drug products described in Orient's ANDA."

54. Orient's filing of ANDA No. 20-5932 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer for sale and/or sale, or the inducement thereof, of its proposed pitavastatin drug product before the expiration of the '993 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

55. Orient's manufacture, use, importation, offer for sale, sale, and/or importation of its proposed pitavastatin drug product will directly infringe or induce infringement of at least one claim of the '993 patent under 35 U.S.C. § 271(e)(2)(A).

56. Unless Orient is enjoined from infringing the '993 patent, plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that making, using, selling, offering to sell and/or importing Orient's pitavastatin drug product for

which it seeks FDA approval or any drug product containing pitavastatin will infringe at least one claim of one or more of the Livalo® patents;

(b) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that the making, using, offering for sale, selling and/or importing of Orient's pitavastatin drug product or any drug product containing pitavastatin, will induce the infringement at least one claim of one or more of the Livalo® patents;

(c) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that the making, using, offering for sale, selling and/or importing of Orient's pitavastatin drug product or any drug product containing pitavastatin, will contribute to the infringement of at least one claim of one or more of the Livalo® patents;

(d) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. and an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for Orient to commercially make, use, sell, offer to sell or import its pitavastatin drug product or any drug product containing pitavastatin be no earlier than the date following the expiration date of the last to expire of the Livalo® patents (as extended, if applicable);

(e) a permanent injunction restraining and enjoining against any infringement by defendant, its officers, agents, attorneys, employees, successors or assigns, or those acting in privity or concert with them, of the Livalo® patents, through the commercial manufacture, use, sale, offer for sale or importation into the United States of Orient's pitavastatin drug product or any drug product containing pitavastatin, and/or any inducement of or contribution to the same;

(f) Attorneys' fees in this action under 35 U.S.C. § 285; and

(g) Such further and other relief in favor of Plaintiffs and against defendant as this Court may deem just and proper.

Dated: May 7, 2014

Respectfully submitted,

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